Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Nigella sativa supplementation on quality of life, Menopausal symptoms and metabolic syndrome among menopausal women

Protocol summary

Summary

This randomized, double blind, placebo controlled trial, will be conducted to asses the effect of Black seed on quality of life, menopausal symptoms and metabolic syndrome parameters among post menopausal women. Totally, 60 menopausal women aged 45–65 years (at least one year after amenorrhea history) who living in Yasuj are recruited. They shouldn't have history of induced menopause following chemotherapy, radiotherapy or surgery; diagnosed cancers; take hormones or anti hypertensive, antihyperlipidemic or diabetic drugs; history of uncontrolled hypertension, myocardial infarction, stroke or have undiagnosed malignancies. The participants will be randomly divided to two groups of placebo and intervention. The intervention and control group will receive 2 gr of Black seed and placebo for 3 months respectively. We will measure B/P, Weight, Height, BMI, body composition, TG, Cholesterol, LDL, HDL, FBS, 17 β Stradiol, as well as Green Climacteric Scale and SF 36 before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111615414N1**
Registration date: **2014-02-20, 1392/12/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-20, 1392/12/01

Registrant information

Name

Saadat Parhizkar

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 74 1222 9224

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nigella sativa supplementation on quality of life, Menopausal symptoms and metabolic syndrome among menopausal women

Public title

Effect of Black seed on Menopause

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria Menopausal women; aged between 45 to 65 years old; who agreed to participate in the study ;living in yasuj. Exclusion criteria Induced menopause following to surgery, chemotherapy or radiotherapy; taking steroid hormones in previous 3 months; taking anti hypertensive, anti diabetic or anti hyperlipidemic

drugs; history of uncontrolled hypertension, MI,or diagnosed cancers.

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Yasuj University of Medical Sciences Ethics Committee

Street address
Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj

City
Yasuj

Postal code
7591994799

Approval date
2013-01-16, 1391/10/27

Ethics committee reference number
91/10/27/8

Health conditions studied

1

Description of health condition studied
Menopausal symptoms

ICD-10 code
O94, O95,

ICD-10 code description
Other obstetric conditions, not elsewhere classified

2

Description of health condition studied
Diabetes

ICD-10 code
E11, E12,

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Menopausal symptoms

Timepoint
at baseline and end of study

Method of measurement
Green Climacteric Scale

Secondary outcomes

1

Description
Quality of Life

Timepoint
at baseline and at the end of study

Method of measurement
SF-36 questionnaire

2

Description
Cholesterol

Timepoint
at baseline and at the end of study

Method of measurement
mg/dl

3

Description
Triglyceride

Timepoint
at baseline and at the end of study

Method of measurement
mg/dl

4

Description
LDL

Timepoint
at baseline and at the end of study

Method of measurement
mg/dl

5

Description
HDL
Timepoint
at baseline and at the end of study
Method of measurement
mg/dl

6

Description
FBS
Timepoint
at baseline and at the end of study
Method of measurement
mg/dl

7

Description
17β Stradiol
Timepoint
at baseline and at the end of study
Method of measurement
pg/dl

8

Description
FSH
Timepoint
at baseline and at the end of study
Method of measurement
miu/ml

9

Description
LH
Timepoint
at baseline and at the end of study
Method of measurement
miu/ml

10

Description
Blood pressure
Timepoint
at baseline and at the end of study
Method of measurement
mmHg

11

Description
weight
Timepoint
at baseline and at the end of study
Method of measurement
kg

12

Description
Height
Timepoint
at baseline and at the end of study
Method of measurement
cm

13

Description
BMI
Timepoint
at baseline and at the end of study
Method of measurement
kg/m2

14

Description
Body composition
Timepoint
at baseline and at the end of study
Method of measurement
Percent

Intervention groups

1

Description
Intervention group: Nigella sativa Capsule 2gr/day
Category
Prevention

2

Description
Control Group: Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zir Tole health Section, Shahid Ashrafi Isfahani Health Center
Full name of responsible person
Fariba Mohammadi
Street address
Alley 2, Golzar Shohada Street, Zir Tole
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Yasuj University of Medical Sciences
Full name of responsible person
Dr Abd Mohammad Moosavi
Street address
Vice chancellor for research, Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Yasuj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Yasuj University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty